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MLN Matters Number: MM5079

Related Change Request (CR) #: 5079

Related CR Release Date: May 19, 2006

Effective Date: October 1, 2006

Related CR Transmittal #: R953CP

Implementation Date: October 2, 2006

Competitive Acquisition Program (CAP) - Creation of Automated Tables for Provider Information, Expansion of CAP Fee Schedule File Layout, and Additional Instructions for Claims Received from Railroad Retirement Board Beneficiaries

Provider Types Affected

Physicians submitting claims to carriers for services to Medicare beneficiaries under the CAP

Impact on Providers

This article is based on Change Request (CR) 5079, which provides additional information and instructions for the implementation of the CAP pertaining to CAP drug categories and fee schedule as outlined in CR4064 (Transmittal 777, dated December 9, 2006).

Background

The Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA, Section 303 (d); <http://www.cms.hhs.gov/MMAUpdate/>) requires the implementation of a competitive acquisition program (CAP) for Medicare Part B drugs and biologicals not paid on a cost or prospective payment system basis. The Social Security Act (Section 1847B(a)(1)(B); http://www.ssa.gov/OP_Home/ssact/title18/1847B.htm) states that for purposes of implementing the CAP:

“The Secretary (of the Department of Health and Human Services) shall establish categories of competitively biddable drugs and biologicals. The Secretary shall

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phase in the program with respect to those categories beginning in 2006 in such manner as the Secretary determines to be appropriate. "

In addition, the Social Security Act also permits the creation of appropriate geographic regions established by the secretary for contract award purposes.

The Centers for Medicare & Medicaid Services (CMS) will implement the CAP with one category of drugs and one geographic area. However, as the program evolves, additional geographic areas and additional drug categories may be created. Also, approved CAP vendors will be able to request approval for changes to the lists of drugs that they supply under the CAP.

CR4064 (Transmittal 777, dated December 9, 2006) described requirements for carriers to develop provider files that list physicians who have enrolled with an approved CAP vendor and the category (or categories) of drugs that the CAP vendor will furnish under the CAP.

CMS is issuing CR5079 to automate the process of updating the list of drugs paid under the CAP. CR5079 provides additional information and instructions for the implementation of the CAP pertaining to the CAP drug categories and fee schedule as outlined in:

- CR4064 (Transmittal 777, dated December 9, 2006 at <http://www.cms.hhs.gov/transmittals/downloads/R777CP.pdf>); MLN Article MM4064 at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM4064.pdf>; and
- CR4309 (Transmittal 866, dated February 6, 2006 (rescinded and replaced with transmittal 866 dated February 17, 2006 at <http://www.cms.hhs.gov/transmittals/downloads/R866CP.pdf>); MLN article MM4309 at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM4309.pdf>.

For the table defined in CR4064.1.1.2.1, when Medicare carriers receive election forms from providers, the carriers will indicate for each provider:

- Which categories of drugs the provider has chosen to receive; and
- From which approved CAP vendor the provider will receive CAP drugs

CAP Drugs and Drug Categories

Approved CAP vendors will be permitted to request certain changes to the list of drugs that they supply under the CAP. Beginning in July 2006 with changes to be effective October 1, 2006, approved CAP vendors may request that CMS (or its designee) approve the following types of changes:

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- **NDC Substitution(s):** Approved CAP vendor may request approval to replace one or more National Drug Codes (NDCs) in a Healthcare Common Procedure Coding System (HCPCS) code supplied by the approved CAP vendor with one or more other NDCs.
- **NDC Addition(s):** Approved CAP vendor may request that CMS allow it to supply additional NDCs under a HCPCS code that the approved CAP vendor already supplies under the CAP.
- **HCPCS Addition(s):** Approved CAP vendor may request that CMS allow it to supply newly issued HCPCS codes under the CAP.
- **Orphan Drugs:** Approved CAP vendor may request that CMS allow it to supply single indication orphan drugs under the CAP.

As CMS continues to develop the CAP, additional geographical areas and additional drug categories may be created. If additional drug categories are created, certain drugs may appear in more than one drug category.

Changes to the Drug List

Written requests for changes to the approved CAP vendor's drug list must be submitted to CMS and the CAP designated carrier. The requests must include a rationale for the proposed change, and a discussion of the impact on the CAP, including safety, waste, and potential for cost savings. If approved, changes will become effective at the beginning of the following quarter. CMS will post the changes on the CMS web site

(<http://www.cms.hhs.gov/competitiveacqisforbios/>) and notify the carriers and participating CAP physicians of any changes on a quarterly basis.

Participating CAP physicians will be notified of changes to their approved CAP vendor's CAP drug list on a quarterly basis and at least 30 days before the approved changes are due to take effect. Physicians who participate in the CAP are required to obtain all CAP drugs, including those that have been added or otherwise updated, from the approved CAP vendor unless medical necessity requires the use of a formulation not supplied by the vendor. Please note that approved changes will apply only to the list of drugs supplied by the approved CAP vendor who submitted the request; therefore, each vendor's drug list may contain different drugs after changes to the initial drug list are approved.

Payment Amount

The payment amount for new HCPCS codes added to an approved CAP drug vendor's drug list will be Average Sales Price (ASP) plus six percent (ASP+ 6%).

Addition or substitution of NDC numbers under an existing HCPCS code supplied by an approved CAP vendor will not change the CAP single payment amount for that HCPCS code.

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CMS will update the single payment amount based on the approved CAP vendor's reported net acquisition costs for the category of drugs on an annual basis.

Disaster Contingency

Business requirements intended to cover situations where an approved CAP vendor is not able to fill CAP orders or is no longer able to supply drugs under the CAP have also been added. Physicians will be able to revert to the ASP (buy and bill) payment methodology.

Claims for Railroad Retirement Board (RRB) Beneficiaries

As claims for RRB beneficiaries can not be paid under the CAP, physicians should not order drugs for RRB beneficiaries under the program. However, should this occur, and the claim is sent to the carrier that processes claims for RRB beneficiaries, that carrier will treat the claim as unprocessable. The physician will have to resubmit the claim as a non-CAP claim with the drugs billed as ASP. The vendor will then have to look to the physician for reimbursement of the drugs that were mistakenly ordered under CAP.

Implementation

The implementation date for the instruction is October 2, 2006.

Additional Information

For complete details, please see the official instruction issued to your carrier regarding this change. That instruction may be viewed at <http://www.cms.hhs.gov/Transmittals/downloads/R953CP.pdf> on the CMS web site.

If you have any questions, please contact your carrier at their toll-free number, which may be found at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.pdf> on the CMS web site.

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